

REMARKS

Examiner has attached hereto amended drawing sheets. The applicant has amended the drawings and the specification to provide proper antecedent basis for the claimed subject matter. No new matter has been added. Applicant respectfully submits that the specification as originally filed provided proper antecedent basis for the claimed subject matter and the amendment to the specification and the drawings. More particularly, the “first position” and “second position” of the claimed subject matter are described on page 6, lines 17 and 18 of the specification as originally filed. The “manual movement” of the detection zone between the first and second positions is described on page 13, lines 20 to 21 of the specification as originally filed. A matrix provided between the sample receiving zone and detection zone as illustrated in new Figure 5 was described in claim 59 (and in lines 6-8 and lines 16-18 of page 12) of the specification as originally filed. A matrix provided in the sample receiving zone as illustrated in new Figure 6 was described in claim 60 (and lines 18-19 of page 12) of the specification as originally filed. The “store of mobile phase” illustrated in new Figure 7 was described in claims 30, 31, 32, 66, 67 and 68 of the specification as originally filed. The use of a separate container for mobile phase illustrated in new Figure 8 was described on page 19, lines 4-6 of the specification as originally filed. Applicant respectfully submits that these issues are now moot.

Applicant has amended the Abstract as requested by the Examiner. Applicant respectfully submits that the objection of the Abstract is now moot.

Applicant respectfully traverses the Examiner's objection of claim 81 as it is not identical to claim 80. Claim 80 defines that the specified materials are located downstream of the sample receiving zone, whereas claim 81 indicates that the materials are located both upstream and downstream of the receiving zone. Accordingly, it is respectfully submitted that these claims clearly define distinct subject matter.

Claims 76, 78, 82, 84, 103 and 104 stand rejected under 35 USC 112, second paragraph as being indefinite. Claims 76, 78, and 103-105 have been cancelled and thus the issues with regard to these claims are now moot. Applicant respectfully traverses the rejection of claims 82 and 84 under 35 USC 112, second paragraph as these claims define features provided by the first and second flow paths, respectively, in a clear and concise manner that does not run afoul of 35 USC 112, second paragraph.

Claims 75-91 and 99-105 stand rejected under 35 USC 102(b) as being anticipated by U.S. Patent No. 5,198,193 to Bunce et al. (hereinafter "Bunce et al.") or by U.S. Patent No. 5,275,785 to May et al. (hereinafter "May et al."). Claims 92-98 stand rejected under 35 USC 103(a) as being obvious over Bunce et al. or May et al. further in view of U.S. Patent No. 5,939,331 to Burd et al. (hereinafter "Burd et al.") Applicant has amended claim 75 to recite the limitations of claim 91. Applicant respectfully submits that the features of claim 75 are not taught or suggested by the cited prior art.

Bunce et al. discloses liquid transfer devices in which a “porous material in a compacted form expandable upon hydration” is used either to bridge a gap in flow channels, or as a switch to change the flow of material between different flow channels. It is clear that it is this expansion of the hydrated material that is responsible for the movement between flow channels, rather than a manual movement as recited in amended claim 75. Indeed, from the “background of the invention” in column 1 of this document it is clear that the devices of Bunce et al. are intended to avoid the perceived difficulties associated with the use of devices involving “complex manual procedures”. This use of hydratable expandable materials is intended to render manual movement of portions of the device unnecessary. In light of the above, amended claim 75 clearly defines novel subject matter over the disclosure of Bunce et al.

May et al. described devices that use a “liquid-swellable material” to make or break contact between two liquid-conductive zones (see lines 1 to 5 of column 2). May et al. does not, contrary to the Examiner’s suggestion, consider a “manually moveable” detection zone, and thus amended claim 75 defines subject matter which is also novel over May et al.

Burd et al. does not remedy the shortcomings of Bunce et al. and May et al.

It is clear from consideration of Bunce et al., May et al. and Burd et al., that the devices described therein are not suitable for manual movement between flow paths. Instead, movement is controlled entirely by hydration and swelling of a material

incorporated in the flow path. It is this swelling which causes movement within the device. Were an operator to attempt to manually switch between flow paths before hydration and swelling of the material, this would cause damage of the material, and would prevent function of the flow path as required. Similarly, the operator cannot readily prevent or delay such switching once hydration of the expandable material has occurred.

Applicant note that that manually moveability of the detection zone provides significant advantages that are not afforded by the cited prior art.

More specifically, manually moveability of the detection zone provides greater “flexibility” for the first incubation. This helps to improve sensitivity and allows thorough “washing” of the detection zone to remove excess analyte and other interfering molecules. Flexibility of this sort cannot be provided by the cited prior art devices. These devices are intended to remove the element of human control and intervention in determining incubation times, instead relying on a “built in” time determined and controlled by selection of the materials used in manufacture. The inability to control incubation times, and thus the degree of “washing” to be achieved, may lead to a high dose hook effect that significantly detracts from the accuracy of the assay.

Manually moveability of the detection zone also enables a completely separated second incubation stage, which allows the particulate reagent to progress along the detection zone in a bolus unaffected by analyte/interfering agents, thus reducing the

likelihood of unwanted prozone or hook effects and improve sensitivity. This advantage is considered, for example, in the second paragraph (lines 14 to 21) of page 11 of the specification as filed, and in lines 1 to 3 of page 14.

The dependent claims 77, 79-90, and 92-102 are patentable over the cited prior art for those reasons advanced above with respect to claim 75 and for reciting additional features that are neither taught or suggested by the cited prior art.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Jay P. Sbröllini". The signature is fluid and cursive, with the first name "Jay" and last name "Sbröllini" clearly distinguishable.

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